

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
)
v.)
)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8545

Bartle, C.J.

September 24, 2010

Celestine Jenkins ("Ms. Jenkins" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support her claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Felton Jenkins, Sr., claimant's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their

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To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In March, 2002, claimant submitted a completed Green Form to the Trust signed by her attesting physician, Winston H. Gandy, Jr., M.D. Based on an echocardiogram dated November 17, 2001, Dr. Gandy attested in Part II of claimant's Green Form that she suffered from moderate aortic regurgitation and had surgery to repair or replace the aortic and/or mitral

3. (...continued)

medical conditions, their ages when they are diagnosed, and the presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

valve(s) following the use of Pondimin® and/or Redux™.⁴ Based on such findings, claimant would be entitled to Matrix A-1, Level III benefits in the amount of \$561,552.⁵

In the report of claimant's November 17, 2001 echocardiogram, the reviewing cardiologist, A. Lucian Cousins, M.D., indicated that claimant had moderate aortic regurgitation. Dr. Cousins, however, did not specify a percentage as to claimant's level of aortic regurgitation. Under the definition set forth in the Settlement Agreement, moderate or greater aortic regurgitation is present where the regurgitant jet height ("JH") in the parasternal long-axis view (or in the apical long-axis view if the parasternal long-axis view is unavailable) is equal to or greater than 25% of the left ventricular outflow tract height ("LVOTH"). See Settlement Agreement §§ I.22. & IV.B.2.c.(2)(a).

4. Dr. Gandy also attested that claimant suffered from moderate mitral regurgitation, an abnormal left atrial dimension, and a reduced ejection fraction in the range of 50% to 60%. As Ms. Jenkins did not dispute the Trust's determination that she had only mild mitral regurgitation, these conditions are not at issue. In addition, Dr. Gandy attested that claimant suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not relevant to the disposition of this claim for Matrix Benefits.

5. Under the Settlement Agreement, an eligible claimant is entitled to Level III benefits if he or she had "left sided valvular heart disease requiring ... [s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." See Settlement Agreement § IV.B.2.c.(3)(a).

In August, 2002, the Trust advised Ms. Jenkins that her claim had been selected for audit.⁶ In response, Ms. Jenkins maintained that she met the requirements for Level III benefits and submitted the tape of an echocardiogram performed on December 15, 1997, which she argued demonstrated mild aortic regurgitation. Ms. Jenkins also conceded that her November 17, 2001 echocardiogram demonstrated aortic stenosis.⁷ In September, 2002, the Trust forwarded the claim for review by Waleed N. Irani, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Irani concluded that there was no reasonable medical basis for the attesting physician's finding of moderate aortic regurgitation. Specifically, the auditing cardiologist observed that "[n]o aortic regurgitation [was] seen."

Based on the auditing cardiologist's conclusion that claimant did not have aortic regurgitation, the Trust issued a

6. Under the Settlement Agreement, Wyeth and the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. & VI.F.; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Policies and Procedures for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. Here, Wyeth identified claimant's levels of mitral and aortic regurgitation, aortic stenosis, and aortic sclerosis. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

7. Under the Settlement Agreement, the presence of aortic stenosis requires the payment of reduced Matrix Benefits. See Settlement Agreement § IV.B.2.d.(2)(c)i)e).

post-audit determination denying the claim. Pursuant to the Audit Policies and Procedures, claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7, PTO No. 2457, and Audit Policies and Procedures § IV.C.⁸ The Trust then applied to the court for issuance of an Order to show cause why the claim should be paid. On February 6, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2746 (Feb. 6, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on April 10, 2003. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor⁹ to review

8. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457. Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to this claim.

9. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In a case such as this, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two

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claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., to review the documents submitted by the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met her burden in proving that there is a reasonable medical basis for her claim. See id. § VI.D. Ultimately, if we determine that there is no reasonable medical basis for this claim, we must affirm the Trust's final determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis for this claim, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of her claim, Ms. Jenkins argues that the auditing cardiologist's determination that her November 17, 2001 echocardiogram does not demonstrate any level of aortic regurgitation is inconsistent with the opinions of three cardiologists. Specifically, claimant notes that, based on a review of her November 17, 2001 echocardiogram, both the attesting physician and the reviewing cardiologist determined she

9. (...continued)
outstanding experts who take opposite positions" is proper. Id.

had moderate aortic regurgitation. Claimant also submits that a separate cardiologist, Richard J. Coralli, M.D., reviewed claimant's December 15, 1997 echocardiogram and determined that she had mild aortic regurgitation. In addition, claimant suggests that there is a reasonable medical basis for Dr. Gandy's representation because her November 17, 2001 echocardiogram indicated the presence of critical aortic stenosis, which is usually associated with aortic regurgitation. Finally, Ms. Jenkins argues that the phrase "left sided valvular heart disease" means that a claimant diagnosed with mild aortic regurgitation, which is considered an FDA Positive¹⁰ condition, may obtain Level III benefits.

In response, the Trust argues that claimant failed to meet her burden of proof because she simply reiterated the attesting physician's findings. The Trust also submits that claimant cannot meet her burden by referring to other echocardiograms and medical records. In addition, the Trust asserts that the level of regurgitation must be determined by a visual examination of the echocardiogram tape, not by relying on "mere statistical probabilities." Finally, the Trust argues that there must be a "causal connection" between a claimant's heart disease and replacement of his or her heart valve. According to

10. FDA Positive is defined, in pertinent part, as "mild or greater regurgitation of the aortic valve" Settlement Agreement § I.22.a.

the Trust, replacement of an aortic valve due to aortic stenosis cannot form the basis for a Matrix claim.

The Technical Advisor, Dr. Vigilante, reviewed claimant's November 17, 2001 echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate aortic regurgitation. In particular, Dr. Vigilante determined that:

This is a good quality study. However, the left ventricular outflow tract is not accurately measured and it is difficult to calculate the aortic valve area from the continuity equation. The aortic valve is heavily calcified and there is marked restriction of the aortic leaflets. There is trace aortic insufficiency with the jet less than 10% of the left ventricular outflow height.

Dr. Vigilante also reviewed claimant's December 15, 1997 echocardiogram and determined that "[m]ild aortic insufficiency was seen."

In response to the Technical Advisor Report, claimant argues that Dr. Vigilante was asked to determine whether her echocardiogram demonstrated moderate aortic regurgitation while the Settlement Agreement only requires "left sided valvular heart disease" to qualify for Level III benefits. According to claimant, at a minimum, an FDA Positive diagnosis should satisfy the requirement of left sided valvular heart disease. Claimant also submits that she is entitled to Level III benefits because Dr. Vigilante determined that her December 15, 1997

echocardiogram demonstrated mild aortic regurgitation and "[t]he fact of her aortic valve replacement surgery is undisputed."

After reviewing the entire Show Cause Record, we find that claimant has established a reasonable medical basis for her claim. Under the Settlement Agreement, a claimant is entitled to Level III benefits for "[s]urgery to repair or replace the aortic and/or mitral valve(s) following the use of Pondimin® and/or Redux™." Settlement Agreement § IV.B.2.c.(3)(a). The Trust maintains that Ms. Jenkins must show that her surgery was necessary because of the regurgitation she suffered, not aortic stenosis. We disagree. Causation generally is not at issue in resolving claims for Matrix Benefits. Rather, claimants must show they meet the objective requirements set forth in the Settlement Agreement. As we previously concluded:

Class members do not have to demonstrate that their injuries were caused by ingestion of Pondimin and Redux in order to recover Matrix Compensation Benefits. Rather, the Matrices represent an objective system of compensation whereby claimants need only prove that they meet objective criteria to determine which matrix is applicable, which matrix level they qualify for and the age at which that qualification occurred....

PTO No. 1415 at 51 (Aug. 28, 2000). In addition, we noted that:

... [Individual issues relating to causation, injury and damage also disappear because the settlement's objective criteria provide for an objective scheme of compensation.

Id. at 97. Here, the Trust does not contest that claimant's aortic valve was replaced or that such replacement occurred

following her ingestion of Diet Drugs. Accordingly, claimant has met the requirements of a Level III claim.

Claimant, however, must also establish her eligibility to receive Matrix Benefits. In PTO No. 3192 (Jan. 7, 2004), we noted that simply meeting the definition of Matrix Level III as set forth in the Settlement Agreement is insufficient to qualify for Matrix Benefits. Rather, a claimant also must satisfy the eligibility requirements set forth in Section IV.B.1.a. of the Settlement Agreement. As we stated, "[e]xperiencing left sided valvular heart disease is of no moment unless the claimant also passes muster under § IV.B.1.a." PTO No. 3192 at 3.

The Settlement Agreement states that the following Class Members are eligible to receive Matrix Benefits:

Diet Drug Recipients who have been diagnosed by a Qualified Physician as FDA Positive or as having Mild Mitral Regurgitation by an Echocardiogram performed between the commencement of Diet Drug use and the end of the Screening Period and who have registered for further settlement benefits by [May 3, 2003].

Settlement Agreement § IV.B.1.a. The Settlement Agreement defines "FDA Positive" as "mild or greater regurgitation of the aortic valve and/or moderate or greater regurgitation of the mitral valve." See id. § I.22. Thus, claimant must establish at least mild aortic regurgitation to be eligible to seek Matrix Benefits for her Level III aortic valve claim.

The report of claimant's December 15, 1997 echocardiogram noted mild aortic insufficiency. In addition, the

Technical Advisor, Dr. Vigilante, reviewed this echocardiogram and concluded that it demonstrated that claimant had mild aortic regurgitation. Despite an opportunity to do so, the Trust does not refute or respond to Dr. Vigilante's conclusions. Claimant, therefore, has presented evidence of having mild aortic regurgitation prior to her surgery.

Under these circumstances, where claimant, pursuant to the Audit Policies and Procedures, submitted her December 15, 1997 echocardiogram in response to the Trust's notification that her claim had been selected for audit and the Technical Advisor reviewed the echocardiogram and determined that it demonstrated the requisite level of regurgitation, we conclude that claimant has met her burden of proving that she is entitled to Matrix B-1, Level III benefits. Accordingly, we will reverse the Trust's denial of the claim for Matrix Benefits submitted by Ms. Jenkins and the related derivative claim submitted by her spouse.